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CE 0459

Reflexonic
Innovative Urological Solutions

Viberect-X3 Penile Vibratory Stimulation System
USER'S GUIDE
Made in USA

EC REP

EMERGO EUROPE
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2513 BH, The Hague
The Netherlands
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Indications for Use:

Viberect® X3 Penile Vibratory Stimulation Device is a hand held medical device indicated to provoke ejaculation in men with spinal cord injury. (Prescription use in the US). Over the counter in all other countries.

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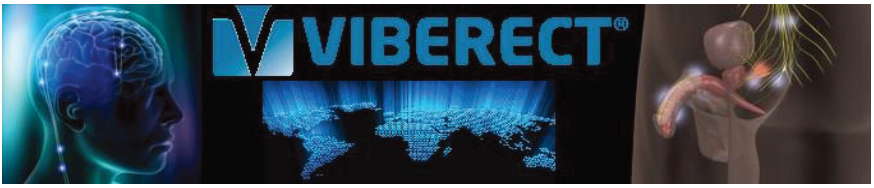

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⚠WARNING: Spinal Cord Injury use carries risk of Autonomic Dysreflexia

PLEASE READ THIS USER MANUAL IN ITS ENTIRETY FOR CORRECT USE AND OPTIMAL RESULTS.

Watch us on YouTube under “Viberect”.

INTRODUCTION

Viberect® penile vibratory stimulation device is a US manufactured hand-held therapeutic vibrator intended to provoke penile erection for erectile dysfunction, and to provoke ejaculation.
Penile vibratory stimulation is an easy and non-invasive nerve stimulation method, similar to sexual intercourse or manual stimulation that helps to activate nerve receptors (nerve antennas) that are located on the skin surface of the penis. These nerves communicate with sexual centers of the brain and spinal cord. Activation and initiation of sexual reflexes by the Viberect device helps to initiate penile erection, rigidity, ejaculation and orgasm. This device is designed by urologists specializing in ejaculation and sexual medicine to help men benefit from this modality with ease in the comfort of their home.

This User’s Guide provides information and instructions which must be followed to ensure safe performance of the **Viberect®** device. This User’s Guide also contains warnings and precautions which must be observed at all times.

CAUTION:

ALL STATEMENTS IN THIS GUIDE SHOULD BE FOLLOWED AT ALL TIMES.

Read the instruction carefully before use.

WARRANTY

Manufacturer guarantees the **Viberect® Device** from mechanical and electrical failure resulting from defective parts and/or workmanship for 12 months from the date of purchase.

The warranty does not cover damage caused by accidents, tampering or alterations of product in any way or due to improper handling, cleaning or misuse of the product or failure to follow the instructions in the User’s Guide. Manufacturer’s liability is limited to the replacement of a defective product.

The Reflexonic company shall not be liable for any incidental or consequential damages whether direct or indirect.

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BATTERY

The battery in your **Viberect®** has not been charged prior to delivery.

A completely discharged battery will take approximately 6-8 hours to fully charge. The Red charge indicator will extinguish once the charge cycle has completed.

To ensure that your Viberect® is always ready for use, it is recommended to recharge the battery after use. Do not leave the device on charger mode for more than 8 hours.

A fully charged battery will allow about 30 minutes of vibration at medium frequency setting.

When completely discharged, allow 6-8 hours to recharge. Ensure that the vibrator is turned off before recharging.

Use only the charger supplied with the vibrator. Charge the Viberect while laying it on its side so the two arms are not brought together by gravity which may turn the device on.

DO NOT ATTEMPT to use the device while charging.

Disposal of the battery

The rechargeable battery in the vibrator contains Nickel Metal Hydride (NiMH).

Like other batteries of this type, if burned or punctured, it could release toxic material which could cause injury.

Device has no replaceable internal power source. Batteries cannot be replaced by the end user. If you wish to dispose of the device, do not disassemble components. Discard in its entirety.

Check with local solid waste officials for details concerning recycling options and proper disposal. In the United States, call toll free 1-800-8-BATTERY or visit the Battery Recycling Corporation website at http://www.call2recycle.org/

The life of NiMH batteries is strongly influenced by the care that they receive. If properly maintained, the battery is capable of more than 500 charge/discharge cycles before dropping to 80% of capacity. Do not exceed the allowable ambient temperatures during charging, operating, or storage.

WARNING
No modification of this equipment is allowed. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

PRECAUTIONS FOR SAFE USE

WARNING: Each Viberect device is intended for use by one person only. It should never be shared by another person, as this will increase risk of communicable or sexually transmitted diseases. Treat your device like a personal toothbrush or other personal hygienic products.

WARNING: This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in presence of unexplained calf pain. Consult your physician.

WARNING: This device should not be used for more than 10 minutes a day to avoid skin injury. Excessive vibratory stimulation can increase risk of skin irritation and temporary numbness.

Vibratory stimulation may cause superficial trauma to the skin resulting in bruising, bleeding or superficial ulceration. If any such condition occurs, refrain from vibrating and consult your physician. Do not immerse the vibrator in any type of fluid. Do not operate the vibrator in bathrooms or elsewhere under wet conditions. If the user is spinal cord injured an episode of autonomic dysreflexia may develop as a result of vibratory stimulation. If so, vibration should be stopped immediately. Consult your physician.

Autonomic dysreflexia (increase in blood pressure, sweating, headaches) may be caused by various factors such as for instance an over distended bowel or urinary bladder. Procedures which involve triggering of orgasm or including vibratory stimulation may precipitate an acute episode of autonomic dysreflexia.

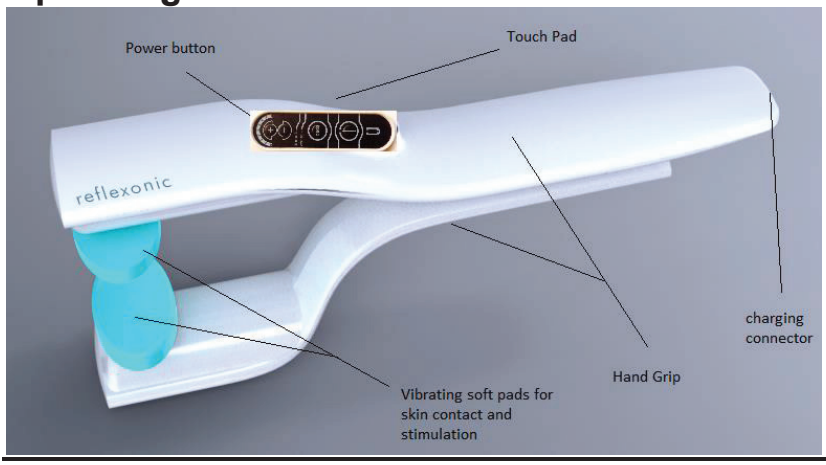
If the user has spinal cord lesion and is above the T6 level the user should obtain careful instructions from your physician concerning autonomic dyreflexia,its potential consequences, and whether vibratory stimulation is acceptable form of treatment.

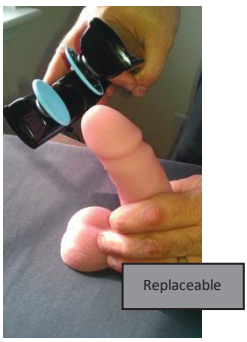
If the user is at risk of experiencing autonomic dysreflexia, it is recommended to use nifedipine (a calcium channel blocker), 10-20 mg, orally, 10-15 minutes before vibration is initiated and to stop vibration immediately at onset of ejaculation.

WARNING
If the user develops penile erection after use of the Viberect device that lasts for more than four hours, consult your physician or go the emergency room immediately, as the user may have developed **Priapism**, which is a medical emergency. Priapism is a medical condition in which poorly oxygenated red blood cells are entrapped in your penis. This requires urgent medical or surgical attention.

WARNING
Avoid Viberect use in temperatures exceeding 35 Cº or 95º F.

VIBERECT® Penile Vibratory Stimulation Device Operating Instructions





Accessories and detachable parts

1. Soft Pads (included) are detachable and replaceable. Soft Pads replacements order *#1680024BK*, provided in pairs.
2. Battery Charger

Touch Pad

(1) ON/OFF button on touch pad

The device may be turned on and off by pressing the button on the touch pad. Hold the on/off button for 3 seconds to turn it off.

(2) FREQUENCY CONTROL

Pressing on the + or – buttons on the touch pad will increase the frequency from 70 Hz to maximum 110 Hz as desired. The LED lights will increase in increments of 5 Hz as visible with red LED lights which progressively turn on from right to left.

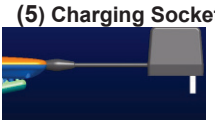
(3) CHARGING INDICATOR

Single red LED light indicates that the Viberect device requires charging. If no red LED light is visible, the device has adequate power for application.

(4) Pad mode button and indicator

The device is capable of 3 modes of operation: 1. Vibrating only the top surface of the penis (Dorsal), 2. Vibrating only the bottom surface of the penis (Ventral), or 3. Both surfaces (recommended for maximal sexual response). The modes can be switched easily while the device is active by pressing on the pads button once, twice, or three times to the desired mode. The LED lights will indicate the modes.

(5) Charging Socket



The charging Socket is located in the back of the device.

DIRECTIONS FOR USE FOR EJACULATION

SPINAL CORD INJURED

CAUTION

If your lesion is above T6 spinal cord level, you must follow your physician's instructions carefully to prevent autonomic dysreflexia.

Autonomic dysreflexia is experienced as a sudden, pounding headache, and a rapid increase in the blood pressure due to excessive activation of the autonomic nervous system. If your spinal cord injury is above the T6 level; your body may have lost ability to automatically control the blood pressure.

It is recommended that at least two vibration procedures are performed in a clinical setting before using the Viberect at home.

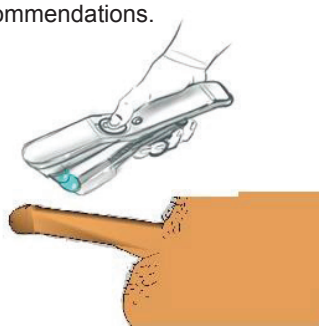
The following initial setting is recommended:

Frequency: 100 Hz
Amplitude: 3 mm (constant)

Place yourself comfortably before turning on the **Viberect®** device

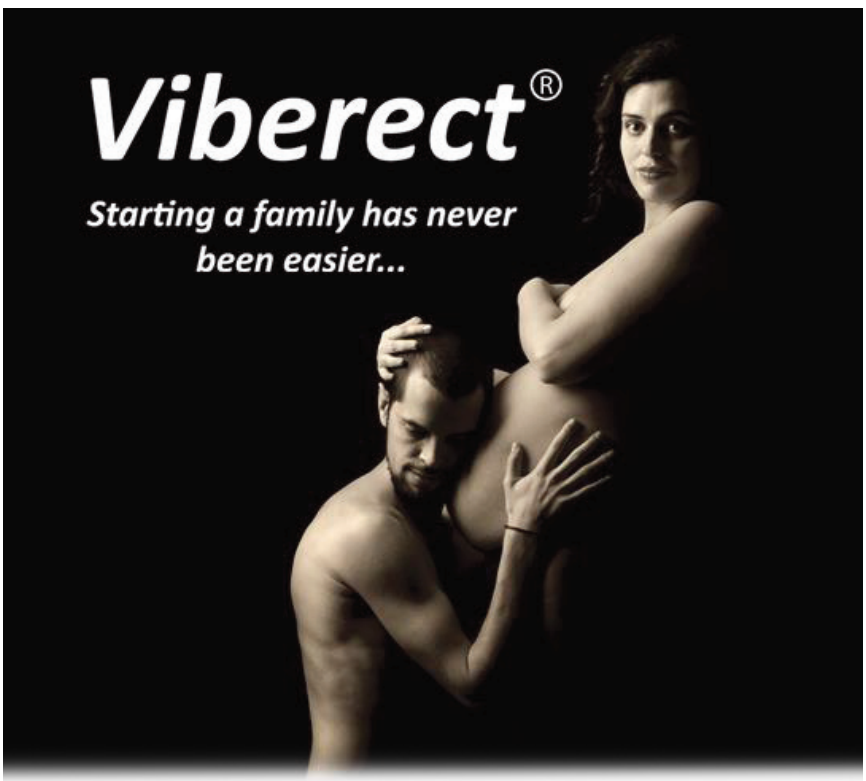
Try lying on a firm mattress, massage table, or even the floor.

Continue vibration until ejaculation occurs or for a maximum of 3 minutes followed by a pause of 1 minute. Speak to your physician for further setting recommendations.



The reflex arch can become exhausted if you stimulate with high amplitude vibration more then 1-2 times every 7-10 days or for more then 3-5 minutes without resting between each attempt.

Success rate can improve significantly if stimulation is properly performed at the head of penis by a trained professional in SCI infertility clinic or a trained spouse. Apply at highest setting for two minutes, followed by rest for two minutes, and another two minutes of stimulation. Be prepared for collecting the specimen with a sterile cup.



TIPS FOR EJACULATION SUCCESS IN MEN WITH SCI

Written by David Buck, Tennis Champion, SCI advocate

I've been using PVS (Penile vibratory stimulation) to ejaculate for over 16 years. When using PVS as a spinal cord injury, brain injury, stoke patient, MS or any man, we need to understand the way we respond to vibratory stimulation. We can typically only have successful ejaculation using the Viberect X-3 or the Ferticare personal using PVS on a once or twice a week basis.

The reflex arch can become exhausted if we stimulate with high amplitude vibration more then 1-2 times every 7-10 days or for more then 3-5 minutes without resting between each attempt.

And when using PVS for the purpose of conceiving children or to collect sperm for future fertility I always recommend taking a full 10 days off from any vibratory stimulation to help insure a positive result the day your spouse is in ovulation, or the day the doctors are collecting your sperm.

Prior to using PVS you should always be in a relaxed state of mind. And in a physical position that triggers spasticity in your lower extremities. If you can't ambulate, and your using a wheelchair on a daily basis. The best position to have success is typically lying flat on your back, allowing the hip flexor to stretch to a flat position. If you have your spouse stimulate the hip flexor with massage while using PVS it can also help trigger the spasticity and help you become more reactive to PVS. You can also have your spouse flex the heel cord (Achilles tendon) while performing PVS to also help trigger spasticity.

If you are using any medications to reduce spasticity, it can directly interfere with your ability to have successful ejaculation as well. So whatever time of day your body is the least affected by these medication will always be the best time to perform PVS.

In some cases the level of medication can be too high to get results at any time of the day or night.

You should always consult with your doctor first, and if they clear you to reduce your dosage or skip a dose of your medication it can be the difference in having successful ejaculation.

In clinical studies spasticity can be reduced or eliminated for 2 hours all the way up to 24 hours after each use. And this is why we need adequate rest between each attempt to ejaculate with PVS.

If you're still not having success, the surface you're lying on may be too soft. Try lying on a firm mattress, massage table, or even the floor. Or you can place something like a stiff foam wedge or anything under your gluteus Maximus (rear end) to stretch the hip flexor beyond 180 degrees to help make the body even more spastic.

PVS will work with a completely flaccid penis (soft penis) and can in some cases work better flaccid then with an erection. After successful ejaculation we can have as much as 1 teaspoon of ejaculate that can remain inside the urethra canal. And with normal intercourse we can actually conceive a child. Or with vaginal or oral sex our spouse can trigger continued ejaculation.

CLEANING

To ensure that your **Viberect®** device is always ready for use, it is recommended to clean both vibrating pads and the entire surface, and to recharge the battery after each use.

Wipe the outside of the vibrator with a dry or alcohol-dampened cloth. Do not immerse the Viberect in any type of fluid.

It is important to wipe off any lotion or moisture off the pads and body of the device after each use with a clean dry cloth and to wipe them with alcohol pads.

Removal and Replacement of Viberect® Soft Pads

If the Viberect Soft Pads start showing any signs of wear and/or degradation, replace them immediately. Specifically, ① check the surface of the pad over-mold for any signs of wear/degradation and replace if needed; and ② check the integrity of the pad-pad over-mold assembly. Simply pull each pad, in the direction directly away from the body of the device (see image). Place new pads by easily snapping them into the pad attachment. Make sure device is in the OFF position when replacing the pads. Dispose old pads in a closed trash container.

Direction of pull to remove touch pads

Viberect Soft Pads or Pad Over-Molds

Additional pads can be purchased from www.reflexonic.com

Guidance and manufacturer's declaration – electromagnetic emissions		
The Viberect device. is intended for use in the electromagnetic environment specified below. The customer or the user of the Viberect device. Should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The Viberect device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Viberect device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network power supply that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Viberect device. is intended for use in the electromagnetic environment specified below. The customer or the user of the Viberect device. should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	Complies	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic sit survey, should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	Complies	
Electrical fast transient IEC 61000-4-4	±2kV power line ±1kV I/O lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential ±2kV common	Complies	
Power frequency magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11	>95% dip 0.5 cycle 60% dip 5 cycles 70% dip 25 cycles 95% dip 5 sec.	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Viberect device.requires continued operation during power mains interruptions, it is recommended that the Viberect device. be powered from an uninterruptible power supply or battery.

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Power Supply:…….....SL Power (AULT) MENB1010A0903F01

Frequency range (with fully charged battery)..... 70 - 110 Hz

Amplitude (peak to peak).....3.0 mm

Battery .....Ni-MH, rechargeable 4 AA

Temperature…..Avoid Viberect use in temperatures exceeding 35º C or 95ºF

Storage……Ambient temperature 68-77ºF (20-25º C)

Symbols Table

Symbol	Meaning
LOT	Batch Code
REF	Catalogue Number
	Consult Instructions for Use
	Type B applied part. " Device provides protection against electrical shock"
	Do not discard device improperly

Symbol	Meaning
	Caution
	Do Not Use if Package is damaged
	Manufacturer and Date of Manufacture
	Fragile

Notes:

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Contact Information:

Customer Service:
Customerservice@reflexonic.com (recommended & most efficient method)
Tel: 001.301.378.8433 9:00 am – 3:00 pm, M-F US-Eastern time
Toll-Free Fax: 800.886.1470

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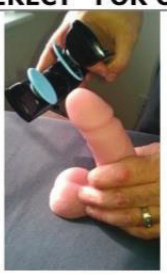
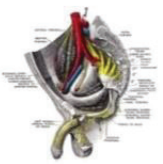
This User Guide is also available in:
Spanish, German, French, Portuguese, Italian
Dutch, Chinese, Polish
www.reflexonic.com

STEP-BY-STEP REFLEXONIC® PRE-VIBERECT® STRETCH EXERCISES AND PROPER APPLICATION OF THE VIBERECT® FOR OPTIMAL SEXUAL RESPONSE

	1. Lie on your back or sit comfortably. *Grasp the head of penis as demonstrated.*		**5. Hold the Viberect® close to the vibrating end and bring the medical Softpads toward the head of the penis.** Attempt different positions. **<u>Standing is very effective position, with penis located below the heart</u>**
	2. Squeeze the head and stretch the penis straight in the air until its natural limit. *You should feel a gentle reflex tightening of your pelvis and penis.*		**6. As you close your grip, the Viberect® automatically activates. Apply pressure.** *You can move the Viberect® to find the most sensitive area.*
	3. Release the stretch back to normal length. *Do not release your grip.*		**7. Now stretch your penis while stimulating with the Viberect® and hold for several minutes (5-10 minutes).**
	4. Repeat steps 2 and 3 every 2-3 seconds for 2-3 minutes.		8. As you stimulate, focus on sexual thoughts and intense past memories, or actual sexual encounters in your life. Let <u>both</u> your penis and the brain stimulate sexual centers in your spinal cord. Relax. Avoid impatience and anxiety.
	The penis gradually becomes engorged with arterial blood and gets increment-ally rigid, exposing nerve antennas for Viberect stimulation**.**		***Warning**: use these instructions at your own risk. Never perform pre-Viberect® & Viberect ® stimulation if you have sores or tears on your penis. Viberect use in men with spinal cord injury carries risk of autonomic dysreflexia*